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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/851,817	05/09/2001	Jochen Wolffgramm	MRI-1	4970

1473 7590 04/20/2004

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EXAMINER	
JIANG, SHAOJIA A	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/851,817	WOLFFGRAMM, JOCHEN	
	Examiner	Art Unit	
	Shaojia A Jiang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 January 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-10 and 13-26* is/are pending in the application.

4a) Of the above claim(s) *2-4,7-10,14-19 and 22-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5,6,13,20,21,25 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is a response to Applicant's amendment and response filed on January 15, 2004 wherein claims 5-6, 13-19, 20-21 and 25 have been amended, and claim 12 is cancelled; claim 26 is newly submitted.

Currently, claims 2-10 and 13-26 are pending in this application.

As recorded in the previous Office Action July 15, 2003, Claims 2-4, 7-10 and 22-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, and Claims 14-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected species.

Claims 5-6, 13, 20-21 and 25-26 as amended now are examined on the merits herein.

Applicant's amendment amending claims 5-6, filed January 15, 2004 with respect to the rejection made under 35 U.S.C. 112 first paragraph for lack of scope of enablement of record stated in the Office Action dated July 15, 2003 has been fully considered and is found persuasive to overcome this particular rejection since the expressions "a corticosteroid receptor agonist" and "an addictive drug" have been removed and the particular agents have been recited in the claims. Therefore, the said rejection is withdrawn.

Applicant's amendment adding the limitation to a kit ...comprising a first receptacle... a second receptacle herein in claims 5, 13, 20-21 and 25 and canceling

claim 12 filed January 15, 2004 with respect to the rejection made under 35 U.S.C. 102(b) as being anticipated by Peyman (WO 9842275) for reasons of record stated in the Office Action dated July 15, 2003 has been considered and found persuasive to overcome this particular rejection. Therefore, the said rejection is withdrawn.

The following is new rejection(s) necessitated by Applicant's amendment filed on January 15, 2004.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5-6, 13, 20-21 and 25-26 as amended now new claim 26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant's amendment submitted January 15, 2004 with respect to amended claims 5-6, 13, 20-21 and 25 and new claim 26 has been fully considered but is deemed to insert new matter into the claims since the specification as originally filed does not provide support for "a kit ...comprising a first receptacle... a second receptacle". The

original specification merely discloses "a pharmaceutical composition", "a pharmaceutical preparation", or "a pharmaceutical formulation" (see for example page 18-19 of the specification). Nowhere can the recitation "a kit ...comprising a first receptacle... a second receptacle" be found in the specification.

Consequently, there is nothing within the instant specification which would lead the artisan in the field to believe that Applicant was in possession of the invention as it is now claimed. See *Vas-Cath Inc. v. Mahurkar*, 19 USPQ 2d 1111, CAFC 1991, see also *In re Winkhaus*, 188 USPQ 129, CCPA 1975.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-6, 13, 20-21 and 25-26 are rejected under 35 U.S.C. 112, second paragraph, for indefinite expressions "a pharmacodynamic equivalent thereof", "a high dose" and "higher amount for the initial dosage", for reasons of record stated in the Office Action dated July 15, 2003.

Applicant's remarks and Exhibit A "The Pharmacological Basis of Therapeutics", (Ninth Edition) filed January 15, 2004 with respect to this rejection made under 35 U.S.C. 112, second paragraph in the previous Office Action have been fully considered but are not deemed persuasive as further discussed below.

Applicant asserts that the recitation "a pharmacodynamic equivalent thereof" does not render the claims herein indefinite according to the definition by the

pharmacology textbook Goodman & Gilman's "The Pharmacological Basis of Therapeutics", Ninth Edition, that defines pharmacodynamics as "the study of the biochemical and physiological effects of drugs and their mechanisms of action" (copy attached as Exhibit A). As such, Applicant argues that a pharmacodynamic equivalent is a compound which will exert an equivalent action via the same mechanism. Applicant's assertion and argument not found persuasive.

In the instant case, as admitted by Applicant that "the study of the biochemical and physiological effects of drugs and their mechanisms of action" is necessary to determine what would be "a pharmacodynamic equivalent thereof". Thus, to practice the claimed invention, one of ordinary skilled in the art would require additional or future research to establish or verify any compounds whether having functions recited in the instant claims and their usefulness.

Genentech, 108 F.3d at 1366, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Moreover, Applicant is seen not to ascertain the metes and bounds as the patent protection desired of "a pharmacodynamic equivalent thereof" as of the instant filing date.

Applicant also argues that the recitations "a high dose" and "higher amount for the initial dosage" are defined in the specification. As noted in MPEP 2111, during patent examination, claims are given their **broadest** reasonable interpretation. It is

proper to use the specification to interpret what the applicant meant by a word or phrase recited in the claim, However, it is not proper to read limitations appearing in the specification into the claim when these limitations are not recited in the claim. See *In re Paulsen*, 30 F.3d 1475, 1480, 31 USPQ2d 1671, 1674 (Fed. Cir. 1994) for example.

In the instant case, one of ordinary skill in the art would not ascertain how high dose would be considered to be "a high dose" and "higher amount for the initial dosage" and what would be the upper limit since any high dose would certainly be harmful or toxic to the human being treated. Hence, one of ordinary skill in the art could not interpret the metes and bounds as to these recitations in the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 5-6, 13, 20-21 and 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peyman (WO 9842275, of record).

Peyman discloses the a pharmaceutical composition, a pharmaceutical preparation, or a pharmaceutical formulation comprising an opioid in combination with the instant preferred corticosteroid receptor agonist such as cortisol, cortisone, prednisolone, and dexamethasone (also known as a glucocrticoid) (see page 8 line 27

to page 9 line 1, and claims 1-2 and 15-17). Peyman discloses broadly that forms of a pharmaceutical composition, a pharmaceutical preparation, or a pharmaceutical formulation therein are nose drops, nasal spray, gel, emulsion, and ointment, e.g., a pharmaceutical composition, a pharmaceutical preparation, or a pharmaceutical formulation therein, can also be made into aerosol formulations to be administered via a nasal spray or nasal inhalation (see page 3 lines 18-19; page 7 line 21-23)

The cited prior art does not expressly disclose a kit comprising the known composition, a pharmaceutical preparation, or a pharmaceutical formulation of Peyman by putting a corticosteroid receptor agonist in a first receptacle and an addictive drug in a second receptacle of a kit.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ a kit to store the known composition, a pharmaceutical preparation, or a pharmaceutical formulation of Peyman by putting a corticosteroid receptor agonist in a first receptacle and an addictive drug in a second receptacle of a kit.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ a kit to store the known composition, a pharmaceutical preparation, or a pharmaceutical formulation of Peyman by putting a corticosteroid receptor agonist in a first receptacle and an addictive drug in a second receptacle of a kit, since various forms of the pharmaceutical composition, preparation, or formulation of Peyman are known to be nose drops, nasal spray, gel, emulsion, and ointment, e.g., to be administered via a nasal spray or nasal inhalation. One of ordinary skill in art

would clearly acknowledge that it is required to store nose drops, nasal spray, gel, emulsion, and ointment in a kit, a container, or a patient pack.

Moreover, a kit, a container, or a patient pack are all deemed obvious since they are all within the knowledge and conventional skills of pharmacologist to conveniently assist the user and prescriber for easy dispensary of the medication.

It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Applicant's arguments filed January 15, 2004 with respect to the rejection made under 35 U.S.C. 102(b) have been considered but are moot in view of the new ground(s) of rejection above.

Additionally, Applicant asserts that "Peyman does not disclose that the sequence of administration of the addictive drug and the corticosteroid is of any importance". However, note the instant claims are not drawn to any method of administration but merely a kit comprising a known pharmaceutical composition, preparation, or formulation. Therefore, the sequence of administration of the addictive drug and the corticosteroid is not considered to be a limitation to a kit.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 5-6, 12-13, 20-21 and 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Capasso et al. (XP-002100182 and XP-002100187, of record) and Montgomery et al. (XP-002100181, of record).

Capasso et al. discloses that a corticosteroid such as the instant preferred corticosteroid receptor agonist, dexamethasone, is capable of inhibiting opioid dependency and thus is useful in a pharmaceutical composition for the treatment of the opioid (opiate) dependency such as morphine by administering an effective amount of dexamethasone before or after the administration of morphine in its effective amount (see two articles entirely, particularly abstract, XP-002100182 at page 743 and the right column of page 746 "Results", and XP-002100187).

Montgomery et al. also discloses that a corticosteroid such as the instant preferred corticosteroid receptor agonist, cortisol, is capable of reducing the severity of morphine withdrawal by administering an effective amount of dexamethasone in 2 mg/kg before or after the administration of morphine, i.e., administering a morphine pellet, 75 mg (see page 454 the left column).

Capasso et al. and Montgomery et al. do not expressly disclose a kit comprising a single composition comprising the particular additive drug in combination with the particular known corticosteroid receptor agonist. Capasso et al. and Montgomery et al.

do not also expressly disclose the employment of the particular corticosteroid receptor agonist, prednisolone, in the treatment for the opioid (opiate) dependency.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to combine the particular additive drug and a known corticosteroid receptor agonist in to a single composition. It would also have been obvious to a person of ordinary skill in the art at the time the invention was made to employ a kit to store the known composition, a pharmaceutical preparation, or a pharmaceutical formulation by putting a corticosteroid receptor agonist in a first receptacle and an addictive drug in a second receptacle of a kit.

One having ordinary skill in the art at the time the invention was made would have been motivated to combine an additive drug and the particular known corticosteroid receptor agonist such as a known corticosteroid, e.g., dexamethasone, cortisol, and prednisolone, in to a single composition since a corticosteroid is known to be useful in a composition and a method of treating the opioid (opiate) dependency based on the prior art. Therefore, one of ordinary skill in the art would have found it obvious to administer an additive drug and a corticosteroid receptor agonist together or combine an additive drug and a corticosteroid receptor agonist such as a corticosteroid, e.g., dexamethasone, cortisol, and prednisolone, in to a single composition to be administered since a corticosteroid is known to inhibit or reduce opioid dependency.

As discussed above, a kit, a container, or a patient pack are all deemed obvious since they are all within the knowledge and conventional skills of pharmacologist to conveniently assist the user and prescriber for easy dispensary of the medication.

Applicant's arguments filed January 15, 2004 with respect to the rejection of 5-6, 12-13, 20-21 and 25 made under 35 U.S.C. 103(a) as being unpatentable over Capasso et al. and Montgomery et al. in the previous Office Action July 15, 2003 have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art as further discussed below.

Applicant asserts that "the teachings of Capasso I, Capasso II and Montgomery differ substantially from the claims of the instant invention" and "in that these documents disclose the use of dexamethasone or cortisol for treating opioid physical dependency, in particular, withdrawal symptoms". Applicant is further requested to note that it is well settled that "intended use" of a composition or product, e.g., the treatment herein, will not further limit claims drawn to a composition or product. See, e.g., *Ex parte Masham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161. Note the instant claims are not drawn to any methods of treatments but merely a kit comprising a pharmaceutical composition, preparation, or formulation. Moreover, the sequence of administration of the addictive drug and the corticosteroid is not considered to be a limitation to a kit, as pointed out above.

Further Applicant's testing of the treatment of the specification at pages 24-31 herein have been fully considered but are not deemed persuasive as to the nonobviousness and/or unexpected results of the claimed invention over the prior art, since they provide no clear and convincing evidence of nonobviousness or unexpected results over the cited prior art since there is no comparison to the same present.

For the above stated reasons, said claims are properly rejected under 35 U.S.C. 103(a). Therefore, said rejections are adhered to.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

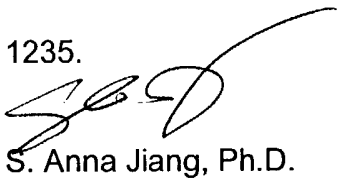
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (571)272-0627. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703.872.9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.



S. Anna Jiang, Ph.D.
Patent Examiner, AU 1617
April 13, 2004